SURGICAL SCALPEL

This application is a Continuation-In-Part of U.S. patent application Ser. No. 09/052,588 filed Mar. 3, 1998, now U.S. Pat. No. 5,938,676 which is a Continuation in Part of U.S. patent application Ser. No. 08/666,734 filed Jun. 18, 1996, now U.S. Pat. No. 5,938,675 which is a Continuation-In-Part of U.S. patent application Ser. No. 08/376,065 filed Jan. 20, 1995 that is now U.S. Pat. No. 5,527,329, issued Jun. 18, 1996, which is a Continuation Application of U.S. patent application Ser. No. 08/163,938 filed on Dec. 8, 1993, abandoned.

The field of the invention is surgical cutting instruments. Conventional surgical instruments provide a significant potential for harm to surgeons, nurses and other support personnel. In the operating room, various surgical instruments are quickly passed by hand. The rapid handling of such instruments with exposed sharp edges can lead to accidental cuts of puncture wounds. Surgical gloves may also be inadvertently punctured leading to loss of glove integrity further increasing the risk of infection to a surgeon, nurse or other medical personnel.

Previous attempts to guard against inadvertent cuts or punctures led to the development of retractable blade guards. Some of the earliest versions were simply retractable bladed knives used in various industries outside the medical field. These blade guards generally required two hands to operate, i.e., one hand to manipulate the blade and a second hand to secure the blade guard by turning a threaded screw. Other conventional devices having spring loaded moving parts or tabs that clipped into notches on a hollow tubed sheathing device, were not practical for surgical use because they did not provide a good grip or "feel" for the blade.

SUMMARY

A surgical scalpel includes an elongate handle defining a longitudinal axis and having a proximal end and a distal end. The scalpel has a cartridge removably mounted to the handle that has a blade holder with a proximal end and a distal end. There is a blade fixedly attached to blade holder disposed so that the blade projects distally outwardly when the cartridge is mounted on the handle. The cartridge also has a shield with a proximal end, a distal end and a bottom mounted onto the blade holder. The shield is slidably movable between a distal position where the shield substantially prevents inadvertent access to the blade and a proximal position where the shield substantially surrounds a portion of the handle and the blade is exposed for use. The cartridge is releasably mountable to the handle and has elements for substantially preventing movement of the shield with respect to the blade holder unless the cartridge is mounted on the handle. The cartridge further includes elements for substantially preventing an inadvertent movement of the shield to the proximal position, thereby to expose the blade as the cartridge is being mounted to the handle.

The scalpel of the invention provides practitioners with a scalpel that has the feel and weighting of a traditional reusable scalpel with the benefits of a fresh blade and a shield that substantially prevents inadvertent access to the sharp blade and that is intuitively movable from the distal position where the blade is protected to the proximal position to expose the blade. The shield of the scalpel of the invention is releasable from the proximal position by the practitioner's direct downward pressure on a digital activation section. The shield includes ergonomic grips to direct the practitioner's hand to a position for mounting the cartridge on the handle where it is unlikely that there will be inadvertent release of the shield for movement from the proximal position where the blade is protected to the distal position where the blade is exposed. The replaceable cartridge that includes the blade allows the personnel charged with arming and disarming the scalpel to handle only a protected blade and substantially prevents operating room personnel from being exposed to the blade during set-ups and transfers of equipment during procedures and substantially prevents exposures to used blades during disarming and clean-up procedures.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, wherein similar reference numbers denote similar elements throughout the several views:

FIG. **1** is an exploded side elevation view of a preferred embodiment of the present scalpel;

FIG. **2***a* is a top view of the blade holder;

FIG. **2***b* is a side elevation view of the blade holder illustrating the position of the hook in the preferred embodiment and illustrating a partial section view of the attachment slot;

FIG. **2***c* is a back end view of the blade holder showing the hook and the attachment slot;

FIG. **2***d* is a front end view thereof;

FIG. **3***a* is a top view of the handle shown in FIG. **1**;

FIG. **3***b* is a side elevation view of the handle illustrating the groove and a male end attachment flange;

FIG. **3***c* is a section view taken along line **3***c*—**3***c* of FIG. **3***b*;

FIG. **3***d* is a front end view of the handle;

FIG. **4***a* is a top view of the sleeve;

FIG. **4***b* is a side elevation view thereof;

FIG. **4***c* is a section view of the sleeve taken along line **4***c*—**4***c* of FIG. **4***b*;

FIG. **4***d* is a front end view of the sleeve showing the arch;

FIG. **5***a* is a side elevation view of the assembled scalpel with the sleeve positioned in an extended position;

FIG. **5***b* is an elevation view thereof with the sleeve in a retracted position;

FIG. **5***c* is a side elevation view with the sleeve removed;

FIG. **6** shows a perspective of an alternative embodiment of the blade holder with the blade attached;

FIG. **7** is a perspective view of an alternative embodiment of the handle;

FIG. **8** is a perspective view of a second alternative embodiment of the handle;

FIG. **9** is a perspective view of an alternative embodiment of the blade holder having a female end connection:

FIG. **10** is a perspective view of an alternative embodiment of the sleeve;

FIG. **11** is a perspective view of an alternative embodiment with the blade holder attached to the handle using vertical slots and tabs;

FIG. **12** is an exploded partial perspective view of an alternative embodiment with the blade holder threaded onto the handle;

FIG. **13** is a perspective view in part section of an alternative handle embodiment having a button for locking the shield in position over the blade;

FIG. **14** is an enlarged section view of the locking button of FIG. **13**;

FIG. **15** is a side elevation view of the button of FIG. **14** locking the shield in its extended position;

FIG. **16** is an exploded perspective view of another embodiment of the scalpel of the present invention;

FIG. **17** is a schematic perspective view of the cartridge portion of the scalpel of FIG. **17**;

FIG. **18** is a partial perspective view of the cartridge being mounted to the handle of to form the scalpel of the invention;

FIG. **19** is a perspective view of the scalpel of the invention with the shield in the distal position;

FIG. **20** is a perspective view of the scalpel of the invention with the shield in the proximal position;

FIG. **21** is a perspective view of the scalpel of the invention with the cartridge partially removed from the handle;

FIG. **22** is a side elevation of the scalpel of the invention analogous to FIG. **21** with the cartridge partially removed from the handle;

FIG. **23** is a partial exploded perspective view showing the removal of the cartridge from the handle; and

FIG. **24** is a perspective view of the blade holder of the invention.

FIG. **25** is an exploded perspective view of a preferred embodiment of the scalpel of the invention;

FIG. **26** is an exploded perspective view of a portion of the scalpel of FIG. **25**;

FIG. **27** is a perspective view of the scalpel of FIG. **25** prior to assembly;

FIG. **28** is a perspective view of the scalpel of FIG. **25** as assembled with the shield substantially preventing inadvertent exposure to the blade;

FIG. **29** is a perspective view of the scalpel of FIG. **25**, analogous to FIG. **28**, with the blade exposed for use;

FIG. **30** is a schematic side elevation view of a portion of the scalpel of FIG. **25**;

FIG. **31** is a schematic side elevation view of another portion of the scalpel of FIG. **25**;

FIG. **32** is a schematic partial horizontal cross section view of the scalpel of FIG. **25** taken from FIG. **28** along the line **32**—**32**;

FIG. **32A** is a schematic side elevation view of a portion of the scalpel of FIG. **25**;

FIG. **33** is a schematic side elevation view of a portion of the scalpel of FIG. **25**;

FIG. **34A** is a side elevation view of a portion of one side of the distal portion of the handle of the scalpel of FIG. **25**;

FIG. **34B** is a side elevation view, analogous to FIG. **34A**, of the other side of the distal portion of the handle of the scalpel of FIG. **25**;

FIG. **34C** is a distal end view of the handle of the scalpel of FIG. **25**;

FIG. **35A** is a side elevation view of one side of the blade holder of the scalpel of FIG. **25**;

FIG. **35B** is a side elevation view, analogous to FIG. **35A**, of the other side of the blade holder of the scalpel of FIG. **25**;

FIG. **35C** is a distal end view of the blade holder of the scalpel of FIG. **25**;

FIG. **35D** is a proximal end view of the blade holder of the scalpel of FIG. **25**;

FIG. **36A** is a cross-sectional view of the shield of the scalpel taken from FIG. **25** along the line **36A**—**36A**;

FIG. **36B** is a cross-sectional view of the shield of the scalpel taken from FIG. **25** along the line **36B**—**36B**;

FIG. **36C** is an end view of the proximal end of the shield of the scalpel of FIG. **25**; and

FIG. **37** is a perspective view of another preferred embodiment of the scalpel of the invention;

FIG. **38***a* is a side elevational view of the shield portion of the scalpel of FIG. **37** taken along the line **38***a,b,c*–**39***a, b,c;*

FIG. **38***b* is a side elevational view of an alternate embodiment of the shield portion, analogous to FIG. **38***a*, of the scalpel of FIG. **37**;

FIG. **38***c* is a side elevational view of yet another alternate embodiment of the shield portion, analogous to FIG. **38***a*, of the scalpel of FIG. **37**;

FIG. **39** is a view of the shield of FIG. **37** taken along the line **39**—**39**;

FIG. **40***a* is a schematic view of the cantilever portion of the shield of the embodiment shown in FIGS. **25**–**36***c;*

FIG. **40***b* is a diagram of the cantilever portion of the shield of the embodiment shown in FIGS. **25**–**36***c*, analogous to FIG. **40***a;*

FIG. **40***c* is a schematic view of the cantilever portion of the shield of the embodiment shown in FIGS. **37**–**39**; and

FIG. **40***d* is a diagram of the cantilever portion of the shield of the embodiment shown in FIGS. **37**–**39**.

DETAILED DESCRIPTION

Turning in detail to the FIGS. **1**–**15**, the surgical scalpel **10** is first shown in FIG. **1** with the blade **12** secured to the blade holder **20**. The scalpel **10** is gripped by the hand **50** which has a preferably contoured elongated grip portion **52**. As is shown in FIGS. **2***a* and **2***b*, adjacent the frond end of the blade holder **20** are two tabs **22** and **24** for securing the blade **12** to the blade holder **20** by inter locking with respective openings on the blade **12**. Adjacent the back end of the blade holder **20** is the attachment slot **26** shown as a female end connection. Channels **28** are positioned longitudinally on opposite sides of the blade holder **20** along a channel section **30** o the blade holder **20**.

A hook **32** is cantilevered from the back end of the blade holder **20**. The hook **32** can resiliently flex upwardly and downwardly to engage the handle **50**. The cantilevered end of the hook **32** has an inclined aft surface **34** and a protrusion **36** which is adapted to engage a complementary shaped grooved **50** on the handle **50** when the blade holder **20** mates with the handle **50**.

Referring now to FIGS. **3***a* and **3***b*, a pair of guide channels **54** are provided on opposite sides of the guide channel section **48** of the handle **50** in front of the grip portion **52**. The guide channels **54** terminate at detents where the guide channel section **48** adjoins the grip portion **52**.

An attachment flange **58** (shown as a male ended attachment is joined to the front end of the guide channel section **48**. As shown in FIGS. **3***b* and **3***d*, the attachment flange **58** is generally rectangular in cross section, although other configurations are possible, and is adapted to mate with the attachment slot **26** of the blade holder **20**. A groove **60** at the forward end of the guide channel section **48** is shaped to mate with the hook **32**.

Next referring to FIGS. **4***a* through **4***d*, the sleeve **70** is generally U-shaped in cross section having a closed bottom portion and an open upper portion. A pair of guide flanges **72** are positioned within the sleeve **70** spans between the two sides of the sleeve **70**. The arch **74** preferably has a radiused front surface **76**.

The sleeve **70** preferably has a digit engaging portion **78** adjacent to the arch **74** having a series of ribs forming a thumb rest. the digit engaging portion **78** improves the surgeon's "feel" for the sleeve **70** when the sleeve **70** slides along the guide channels **28** and **54** by hand or thumb pressure. FIG. **5***a* shows an assembled scalpel **10** with the sleeve **70** in a forward position to cover of sheath the blade **12**. The forward movement of the sleeve **70** is guided by the guide flanges **72** that travel along the guide channels **28** and **54**. With the sleeve **70** moved fully forward, the radiused surface **76** contacts the hook **32** to stop additional forward movement.

Additional forward movement by the sleeve **70** toward the extended position as guided by the user's hand will cause the arch **74** to lift the hook **32** out of the groove **60** for removal of the blade holder **20** from the handle **50**. This allows the sleeve **70** and blade holder to be disassembled as a unit from the handle **50** while the blade **12** is sheathed by the sleeve **70**, thus minimizing the risks of inadvertent cuts. The blade **12**, blade holder and sleeve **70** may then be disposed of. the handle may advantageously be reused.

FIG. **5***b* shows the sleeve **70** moved to the fully retracted position with the back end of the sleeve **70** abutting the detents **56** to fully expose the blade **12**. the user may utilize the digit engaging portion **781** on the sleeve **20** to improve fingertip control of the longitudinal front to back movement of the sleeve **70**. FIG. **5***c* shows the sleeve **70** removed from the handle **50** (for purposes of illustration).

FIG. **6** illustrates an embodiment of the blade holder **20** with both a male ended attachment and a female ended slot. FIG. **7** shows an embodiment of the handle **50** which mates with the blade holder **20** shown in FIG. **6**. An alternative embodiment of the handle **50** is also shown in FIG. **8** with male ended connections. An embodiment of the blade holder **20** which mates with the handle **50** of FIG. **8** is further shown in FIG. **9** with an outline of the attached blade **12**. An alternative embodiment of the sleeve **70** is shown in FIG. **10** which illustrates a stop tab **80** which may be utilized to stop forward longitudinal sliding of the sleeve **70**. An inclined digit engaging portion **78** is illustrated and may be used to facilitate use as a thumb rest for the operation surgeon.

In an alternative embodiment **90** as shown in FIG. **11**, a handle **92** has a flange **94** with vertical tabs or protrusions **96**. A blade holder **98** has internal vertical slots **100** adapted to vertically slide down over the tabs **96**, from above. A sleeve **102** is secured to the blade holder **98**, as described above with reference to FIGS. **1–5**. The sleeve **102** has a slot **104** at the back end of its lower surface. In use, the blade holder **98** is attached to the handle **92** by engaging the vertical tabs **96** into the vertical slots **100**, by sliding the blade holder **98** down onto the handle **92** from above. the slot **104** in the bottom of the sleeve **102** provides sufficient clearance for the protruding vertical tabs **96**.

Turning to FIG. **12**, a surgical scalpel **110** has a handle **112** with a threaded stud **114** at its front end. The stud **114** threads into a threaded hole **118** at the back end of a blade holder **116**. The threads on the stud **114** and in the threaded hole **118** are advantageously cut so that when the blade holder **116** bottoms out of the front end of the handle **112**, the blade holder **116** will be properly vertically aligned. A sleeve **119** overlies the blade holder **116**. The operation and design features of the surgical scalpels shown in FIGS. **11** and **12** are similar to the embodiment in FIGS. **1–5**, except as described above.

As shown in FIG. **13** an alternative handle embodiment **122** has a locking button **124**. As shown in FIG. **14**, the locking button **124** has a shoulder **126** which fits within a bore **130** in the handle **122**. A plug or set screw **134** at the top of the handle **122** retains a spring **128** in the bore **130**, with the spring **128** biasing the locking button **124** to protrude out of the bottom surface of the handle **122**. Referring to FIG. **15**, with the shield **70** fully extended to cover the blade, **12**, the locking button **124** protrudes out of the bottom of the handle **122**. The sleeve **70** can not be retracted to expose the blade, without first pushing the locking button **124** up into the bore **130**. Once the locking button is pushed up into the bore, the sleeve may be retracted, with the locking button sliding in the inside lower wall or surface of the sleeve. Accordingly, the locking button **124** helps to prevent inadvertent exposing of the blade **12**. The locking button feature may be used on any of the surgical scalpel embodiment described above.

While a preferred embodiment of the present invention has been shown and disclosed in the drawings and specifications, alternate embodiments of the present invention would be apparent to the person of ordinary skill in the art and this application is intended to include those embodiments within the full breadth and scope of the claims. Moreover, the present invention need not include all of the features disclosed in the single embodiment but rather one or more features may be included.

While this invention is satisfied by embodiments in many different forms, there are shown in the drawings and herein described in detail, embodiments of the invention with the understanding that the present disclosure is to be considered as exemplary of the principles of the present invention and is not intended to limit the scope of the invention to the embodiments illustrated. The scope of the invention is measured by the appended claims and their equivalents. In this disclosure, the term "proximal" refers to the portions of the device closest to the practitioner and the term "distal" refers to the portion of the device away from the practitioner.

Referring to FIGS. **16–24**, a surgical scalpel **310** of the present invention includes an elongate handle **312** defining a longitudinal axis "A" has a proximal end **314** and a distal end **316**. Scalpel **310** has a cartridge **318** removably mounted to handle **312** that includes a blade holder **320**. Handle **312** has a first portion **322** having a first crosssectional area "X" with a first side **324** and an opposed second side **326**, a second portion **328** having a larger cross-sectional area "Y" than said first portion **322** and a third portion **329** having a larger cross-sectional area "Z" than second portion **328**. Blade holder **320** has a proximal end **330** and a distal end **332**. Referring to FIG. **18**, proximal end **330** has an elongate cavity **334** therein for releasably receiving first portion **322** of handle **312** thereby removably mounting cartridge **318** to handle **312**. Cartridge **318** includes a blade **336** that is fixedly attached to blade holder **320** so that when cartridge **318** is mounted to handle **312**, blade **336** projects distally outwardly. Cartridge **318** further includes a shield **338** mounted on blade holder **320**. Shield **338** is slidably movable between a distal position, best seen in FIG. **19**, with shield **338** positioned to prevent substantially inadvertent access to blade **336** and a proximal position, best seen in FIG. **20**, where shield **338** substantially surrounds second portion **328** and third portion **329** of handle **312** and blade **336** is exposed for use. Shield **338** has a releasable latch **340** for retaining shield **338** in the distal position and the proximal positions.

As shown in FIG. **18**, first side **324** and said second side **326** of first portion **322** of handle **312** each include at least one outward projection **342** thereon. Cavity **334** further includes opposed sidewalls **344** and **346** with recesses **348**

that are disposed to engage each of outward projections **342** on first portion **322** of the handle when handle **312** is received into cavity **334** in the blade holder from a direction generally orthogonal to longitudinal axis "A" and shield **338** is in the distal position. Referring now to FIGS. **21**, **22** and **23**, cartridge **318** is dismountable from handle **312** by disengagement of recesses **348** from projections **342** by removal of cartridge **318** from the handle in an axial distal direction by an outward deflection of sidewalls **344** and **346** of cavity **334** when shield **338** is in the distal position. When shield **338** is in the proximal position, sidewalls **344** and **346** are substantially precluded from outward deflection by the presence of shield **338**, thus retaining the cartridge on the handle. Additionally, outward projections **342** are preferably disposed and shaped to facilitate the placement of cartridge **318** into cavity **334** from the direction orthogonal to the axis "A" and shaped to substantially resist the opposite orthogonal movement to axis "A" to remove the cartridge from the cavity. Thus, a force to remove cartridge **318** from cavity **334** in a direction orthogonal to axis "A" is greater than the force required to place the cartridge onto the handle.

Shield **338** is selectively retained in the proximal and distal positions by a latch that includes at least one, preferably two grooves **350**, that extend from distal end **332** to said proximal end **330** of blade holder **320** on opposite sides of the blade holder. Grooves **350** continue into second portion **328** of handle **312**. Grooves **350** each include a distal stop **352** in blade holder **320** and a proximal stop **354** in second portion **328**. Shield **338** includes a cantilever **356** that has at least one, preferably two, inward projections **358** that are sized and positioned to fit within grooves **350** and engage distal stops **352** when shield **338** is in the distal position, and engage proximal stops **354** when shield **338** is in the proximal position. Cantilever **356** has a digit press surface **360** projecting upwardly, so that a practitioner's digital pressure sufficient to deflect cantilever **356** downwardly disengages projections **358** from one set of stops to allow the practitioner selectively to move shield **338** between the proximal position and the distal position. Referring to FIGS. **16** and **18**, that show how first portion **322** is fit within cavity **334** to mount cartridge **318** to handle **312** and latch **340** that retains shield **338** in the proximal position until cantilever **356** is deflected, shield **338** is substantially unlikely to be moved to the proximal position inadvertently. Movement of shield from the proximal position requires both deflection of cantilever **356** to disengage projections **358** from the proximal stops **354** followed by proximal movement of the shield. When handle **312** is not present, even if cantilever **356** is deflected sufficiently to disengage projections **358** from proximal stops **354**, there is nothing to push against to move the shield proximally with respect to blade holder **320** to move shield proximally and inadvertently expose blade **336**.

Grooves **350** have a first depth "a" between distal end **332** of blade holder **320** and distal stops **352** and a second depth "b" between distal stops **352** and proximal stops **354**, second depth "b" being deeper than first depth "a" so that as cartridge **318** is assembled by placement of a proximal end **337** of shield **338** onto blade holder **320** distal end **332** with inward projections **358** positioned in grooves **350**, a proximal axial movement of shield **338** outwardly deflects inward projections **358** until the projections reach distal stop **352** whereupon projections **358** reach second depth "b" and are no longer deflected thereby serving to retain shield **338** on blade holder **320**. When cartridge **318** is not mounted to handle **312**, deflection of cantilever **356** can only disengage projections **358** from distal stops **354**, movement of the projections back into the portion of grooves **350** with depth "a" would require use of some sort of a tool, thus substantially preventing inadvertent distal movement of the shield, removal of the shield from the blade holder and inadvertent exposure of the blade.

Blade holder **320** further includes at least one, preferably two, channels **362** extending from distal end **332** of blade holder **320** to second portion **328** of handle **312** when cartridge **318** is mounted on handle **312**. Shield **338** includes at least one, preferably two rails **364** sized and positioned to cooperatively slide within channels **362** thereby to facilitate movement of shield **338** between the proximal and the distal positions.

Referring to FIG. **24**, blade holder **320** includes an outward projection **366** sized and shaped to fit an aperture **367** in blade **336** for mounting blade **336** to the blade holder. Blade **336** may be fixedly attached to the blade holder **320** by heat staking, adhesive bonding or any other type of attachment known to be satisfactory for forming such an attachment. It is the intention of the invention that blade **336** not be removable from the blade holder without rendering the blade holder substantially non-functional. Preferably, blade **336** is fixedly attached to blade holder **320** by a heat staking process to provide the fixed and substantially rigid attachment of the blade that is required by practitioners. Blade **336** may be any size or shape blade commonly used for surgical procedures and formed from any materials commonly used for such blades. Preferably, blade **336** is formed from a stainless steel and sharpened to a fine cutting edge.

Blade holder **320** may be formed from thermoplastic materials such as polypropylene, polyethylene, polycarbonate, polysulfone, polyacetal, polyamide and the like. Shield **338** may be formed from thermoplastic materials such as polypropylene, polyethylene, polycarbonate, polyacetal, and polyamide and the like. For particular applications shield **338** may be formed from a substantially transparent material. Handle **312** may be formed from a material such as machined metal, formed powdered metal and thermoplastic or thermoset materials. In the preferred application, shield **338** and blade holder **320** are formed from thermoplastic materials such as polypropylene and polycarbonate with a stainless steel blade to form the single-use cartridge **318**. flandle **312** preferably is formed from machined metal or formed powdered metal to provide a durable reusable device that provides the practitioners with the same "feel" and "heft" that they are accustomed to with the current reusable handles and with removable single-use bare blades. Handle **312** preferably has a surface treatment, here illustrated as knurling **313**, to improve the practitioner's ability to securely grip the scalpel. Other surface treatments including roughening, grooving, checkering and the like may be preferred for particular applications and are considered within the scope of the invention.

Preferably, cartridge **318**, with shield **338** in the distal position where blade **336** is protected, is placed in a package **370**, indicated in phantom in FIG. **17**, formed from materials substantially resistant to the passage of microorganisms and package **370** is sealed. Preferably, sealed package **370** is then exposed to conditions that would render any microorganisms inside the package substantially non-viable. Packaged cartridges then may be considered "sterile" until the package is opened to arm the reusable handle. Preferably, the handles are subjected to a cleaning and sterilization process by the practitioner prior to their presentation for the cartridge loading. Suitable materials for forming package **370** include, but are not limited to, paper, nonwoven materials such as spun-bonded polyolefin and the like, polymeric films, metal-

lic foils and composites of these materials. Suitable techniques for rendering microorganisms within package **370** non-viable include, but are not limited to, exposure to chemical agents such as ethylene oxide, gaseous hydrogen peroxide and the like, ionizing radiation, such as gamma radiation from Co^{60}, electron beam radiation, dry heat and steam sterilization. When selecting materials for forming scalpel **310** and package **370**, consideration of the particular materials' tolerance for the sterilization method should be made.

A method for using scalpel **310** includes opening package **370** to expose a proximal end **319** of cartridge **318**. Handle **312** is then fitted to the cartridge and removed from the package. Depending upon the choice of the individual practitioner or the institution use protocol, scalpel **310** may be passed to the practitioner with shield **338** in the distal position as it is removed from package **370**. Upon receiving scalpel **310**, the practitioner applies digital pressure to press surface **360** to disengage projections **358** from distal stops **352** and withdraw shield **338** to the proximal position to expose blade **336** for the desired procedure. After the practitioner has completed the procedure, the practitioner applies digital pressure to press surface **360** to disengage projections **358** from proximal stops **354** and return shield **338** to the distal position to pass scalpel **310** to the support person with blade **336** protected from inadvertent exposure. With shield **338** in the distal position, the support personnel may then remove cartridge **318** from handle **312** and dispose of it according to the institution protocol. Handle **312** may then be subject to cleaning and sterilization according to the institution protocol and returned for further use.

An alternative for particular applications, is to form handle **312** from similar materials as blade holder **320**, mount cartridge **318** to handle **312**, complete the desired procedure, and then dispose of entire scalpel **310** after the procedure is completed.

Referring now to FIGS. **25–36C**, a more preferred embodiment of the scalpel **410** of the invention includes an elongate handle **412** defining a longitudinal axis "A" that has a proximal end **414** and a distal end **416**. Scalpel **410** further includes a cartridge **418** that is removably mounted to handle **412**. Cartridge **418** has a blade holder **420** with a proximal end **422** and a distal end **424** with a blade **426** fixedly attached that is disposed so that blade **426** projects distally outwardly when cartridge **418** is mounted to handle **412**. Cartridge **418** also includes a shield **430** that is releasably slidably mounted onto blade holder **420** for movement between a distal position, best seen in FIG. **28**, where shield **430** substantially prevents inadvertent access to blade **426** and a proximal position, best seen in FIG. **29**, where shield **430** substantially surrounds a portion of handle **412** and blade **426** is exposed for use. Cartridge **418** is releasably mountable to handle **412**. Additionally, shield **430** is substantially not moveable with respect to blade holder **420** unless cartridge **418** is mounted on handle **412**.

Shield **430** includes a cantilever **432** with a digital activation section **434** projecting upwardly from a top surface **435** of the shield. When cartridge **418** is mounted on handle **412**, a practitioner may apply digital pressure to digital activation section **434** sufficient to downwardly deflect cantilever **432** and release shield **430** for movement between the proximal position and the distal position. Scalpel **410** has a groove **436** that extends from the blade holder **420** from a distal terminus **438** onto handle **412** to a proximal terminus **440** on one side of the scalpel. Preferably, scalpel **410** has a groove **436** on each of a first side **437** and a second side **439**, each with distal termina **438** on blade holder **420** and proximal termina **440** on handle **412**. Cantilever **432** further includes at least one boss **442**, preferably two bosses **442** disposed to engage each of grooves **436**. Each termina of groove **436** is an upward enlargement disposed to engage bosses **442** when shield **430** is positioned in either the proximal or distal positions. When bosses **442** are engaged in the termina, shield **430** is substantially prevented from movement. When the practitioner applies sufficient downward force to digital application section **434** to deflect cantilever **432**, bosses **442** are no longer engaged with the upward enlargements at the terminal thereby allowing the practitioner to selectively move shield **430** between the proximal and distal positions as desired. Bosses **442** track in grooves **436** to stabilize shield **430** during the movement between positions, and when a terminus is reached, bosses **442** preferably serve to provide a practitioner perceptible "snap" as the bosses engage the enlargement and allow cantilever **432** to return to the rest position to assist the practitioner in recognition of the completion of desired movement of the shield.

Cartridge **418** is preferably supplied sealed in a package **446**, illustrated in phantom in FIG. **27**, formed from materials substantially resistant to the passage of microorganisms and exposed to conditions that render any microorganisms within package **446** substantially non-viable. Suitable materials for forming package **446** include. but are not limited to, paper, polymeric films, non-wovens, metallic foils, and combinations of these materials. Suitable conditions for rendering microorganisms non-viable include, but are not limited to, chemical agents such as ethylene oxide and gaseous hydrogen peroxide, ionizing radiation such as gamma, electron beam, ultra-violet and the like.

Cartridge **418** is supplied separately and includes blade **426**, which is preferably formed from a material such as stainless steel. carbon steel or a ceramic that is suitable for being formed to a sharpened edge for cutting. Shield **430** is substantially not movable with respect to blade holder **420** unless cartridge **418** is properly fully mounted on handle **412** and the practitioner handling the scalpel is intentionally moving the shield. Practitioners and service personnel are thus substantially protected from inadvertent exposure to the blade during assembly of the cartridge to the handle, during handling to prepare for or after a procedure, or during clean-up and disposal of a cartridge after removal from the handle.

Shield **430** preferably includes a deflectable tab **450**, best seen in FIGS. **27**, **28**, **32** and **32A**, with an inwardly projecting lug **452** that is disposed to engage a seat **454** in blade holder **420**. Seat **454** is best seen in FIGS. **26**, **33** and **35B**. During initial assembly of cartridge **418**, preferred blade **426** with an aperture **456** is fixedly attached to an outward protuberance **458** on blade holder **420** by fitting aperture **456** over protuberance **458** so that blade **426** is substantially rigid with respect to blade holder **420**. Suitable fixed attachments of blade **426** to blade holder **420** are formed by heat staking the projection onto the aperture, adhesive bonding or the like. Shield **430** has a proximal end **460** and a distal end **462**. The assembly then includes substantially axially aligning proximal end **460** of the shield with distal end **424** of the blade holder and proximally advancing the shield onto the blade holder to form cartridge as shown in FIG. **25**. As is best seen in FIGS. **35A**, **35B**, **35C** and **35D** grooves **436** have a first depth "a" between distal termina **438** on the blade holder and a second depth "b" between distal termina **438** and distal end **424** of the blade holder. Second depth "b" is less than first depth "a" thereby to form a shoulder **464** at the intersection of depths "a" and

"b". As shield **430** is proximally advanced onto blade holder **420**, bosses **442** engage grooves **436** at second depth "b" and deflect. As shield **430** is further proximally advanced onto the blade holder, bosses **442** engage deeper first depth "a" at distal termina **438** and are substantially prevented from returning to second depth "b" region by shoulder **464** thereby substantially preventing distal movement of shield **430** with respect to blade holder **420**. Tab **450** with inwardly projecting lug **452** is disposed to engage seat **454** in blade holder **420** when bosses **442** are in distal termina **438**, thus substantially preventing further movement of shield **430** with respect to blade holder **420** until cartridge **418** is mounted onto handle **412**.

Preferably, shield **430** is substantially prevented from movement with respect to blade holder **420** during mounting of cartridge **418** onto handle **412** even if the practitioner unintentionally applies sufficient pressure to digital activation surface **434** to deflect cantilever **432**. Proximal end **414** of handle **412** is preferably disposed to engage at least one of bosses **442** as cartridge **418** is proximally advanced onto handle **412** when cantilever **432** is deflected downwardly. Additionally if the practitioner were to inadvertently apply pressure to digit activation surface **434** after cartridge **418** is partially properly advanced onto handle **412**, preferred handle **412** further includes a recess **466** disposed on a top surface **467** of handle **412** to engage at least one of bosses **442** to function as a false stop and substantially prevent further advancement of cartridge **418** onto handle **412**.

As cartridge **418** is fully seated on handle **412**, a distal prong **478** on handle **412** with a chamfered surface **470** is preferably disposed to engage tab **450** and disengage inwardly projecting lug **452** from seat **454** on blade holder **420**, thus allowing movement of shield **430** with respect to blade holder **420** when the practitioner intentionally applies sufficient pressure to digital activation surface **434** to downwardly deflect cantilever **432**. Preferably, distal prong **478** is stiffened by a rib **479** on one side.

Cartridge **418** is releasably mounted to handle **412** by engaging a downward projection **480** on handle **412** with a pocket **482** on a flexible beam portion **484** that projects proximally from blade holder **420**, best seen in FIGS. **25**, **26**, **30**, **31** and **32A**. To remove cartridge **418** from handle **412**, cartridge **418** is distally advanced from handle **412**. Preferably, shield **430** substantially surrounds blade holder **420** and substantially prevents inadvertent access to blade **426** when shield **430** is in the distal position, as best seen in FIG. **28**. When shield **430** is proximal position, as best seen in FIG. **29**, blade **426** is exposed for use, bosses **442** are disposed in proximal termina **440** and shield **430** surrounds at least a portion of handle **412**. Since shield **430** substantially surrounds at least a portion of the handle when is in the proximal position, beam **484** is substantially prevented from flexing downwardly to release projection **480** from pocket **482** by the shield, thus substantially preventing cartridge **418** from being dismounted from handle **412** when the blade is exposed. Additionally, if a practitioner inadvertently applies distal force to attempt to move the shield to the distal position, the presence of bosses **442** in proximal termina **440** substantially prevent movement of shield **430** to the distal position. To move shield **430** to the distal position, the practitioner must apply sufficient force to the digital activation surface **434** to downwardly deflect cantilever **432** and release bosses **442** from the proximal termina **440**. If a practitioner grasps shield **430** and attempts to remove cartridge **418** from handle **412** after shield **430** is released from the proximal position, but before shield **430** is fully seated in the distal position and blade **426** is substantially protected from inadvertent access, shield **430** substantially prevents the disengagement of pocket **482** from projection **480** until the shield is distally advanced to substantially protect blade **426** from inadvertent access. Then, as handle **412** is separated from cartridge **418**, prong **478** is disengaged from tab **450** thereby allowing lug **452** to engage seat **454** and substantially prevent movement of shield **430** with respect to blade holder **420**.

Preferably, shield **430** includes inwardly projecting rails **486** disposed to slidably engage conjugate slots **488** on both sides of blade holder **420** and handle **412** to provide stability to shield **430** during movement between the proximal and distal positions and to improve the overall rigidity and feel of scalpel **410** in the practitioner's hand.

Blade holder **420** may be formed from materials such as polymeric resins or metallic materials. Preferably, blade holder **420** is formed from thermoplastic materials such as polypropylene, polyethylene, polycarbonate, polysulfone, polyacetal, polyamide and the like. Shield **430** may be formed from thermoplastic materials such as polypropylene, polyethylene, polycarbonate, polyacetal, polyamide and the like. For particular applications, the material selected to form shield **430** may be substantially transparent. Handle **412** may be formed from thermoplastic materials such as polyethylene, polycarbonate, polysulfone, polypropylene, polyacetal, polyamide and the like. Preferably, handle **412** is formed from a metallic material such as formed powdered metal or machined metal. Preferably materials are selected to provide a substantially rigid structure for scalpel **410** that are compatible with most sterilization methods and provide practitioners with a scalpel that has similar "feel" and "balance" to current reusable devices or reusable handle devices intended to mount and dismount bare single-use blades.

In normal use, practitioners would receive cartridge **418** sealed in package **446**. A method for assembling scalpel **410** includes opening package **446** to expose cartridge **418**, and positioning the cartridge so that proximal end **422** of the blade holder is in substantial axial alignment with the distal end of handle **412**. The practitioner then advances the cartridge proximally onto the handle until it is fully seated. At this point, the practitioner may apply finger pressure to the digital activation surface to downwardly deflect the cantilever and release the shield for movement from the distal position to the proximal position to expose the blade for use. After the use of the blade is complete, the practitioner releases the shield from the proximal position with finger pressure and moves shield **430** to the distal position. The practitioner then grasps the shield, applies distal force and removes the cartridge from the handle for disposal according to the institution's disposal protocol.

The scalpel of the invention provides practitioners with a scalpel that has the "feel" and "heft" of traditional reusable scalpels while additionally providing both practitioners and support personnel with a shielded blade that is unlikely to be inadvertently exposed. The removable cartridge allows the use of a sterile sharp blade for the procedure and substantially allows the blade to be protected from inadvertent exposure both during preparation for the procedure and after the procedure.

Referring now to FIGS. **37–40***d*, a further preferred embodiment of the scalpel of the invention is shown. In this embodiment, elements of the invention are substantially similar to those of the embodiment shown in FIGS. **25–36***c*. Accordingly, substantially similar elements that perform substantially similar functions are assigned similar reference

characters of the "5" hundred series. Scalpel **510** of the invention includes an elongate handle **512** defining a longitudinal axis "A" that has a proximal end **514** and a distal end **516**. Scalpel **510** further includes a cartridge **518** that is removably mounted to handle **512**. Cartridge **518** has a blade holder **520** with a proximal end **522** and a distal end **524** with a blade **526** fixedly attached that is disposed so that blade **526** projects distally outwardly when cartridge **518** is mounted to handle **512**. Cartridge **518** also includes a shield **530** with a proximal end **560** and a distal end **562** that is releasably slidably mounted onto blade holder **520** for movement between a distal position, similar to that shown for the previous embodiment shown in FIG. **28**, where shield **530** substantially prevents inadvertent access to blade **526** and a proximal position, similar to that shown for the previous embodiment in FIG. **29**, where shield **530** substantially surrounds a portion of handle **512** and blade **526** is exposed for use. Cartridge **518** is releasably mountable to handle **512**. Additionally, shield **530** is substantially not moveable with respect to blade holder **520** unless cartridge **518** is mounted on handle **512**.

Shield **530** includes a first cantilever **532** with a digital activation section **534** projecting upwardly from a top surface **535** of the shield. When cartridge **518** is mounted on handle **512**, a practitioner may apply digital pressure to digital activation section **534** sufficient to downwardly deflect cantilever **532** and release shield **530** for movement between the proximal position and the distal position. Scalpel **510** has a groove **536** that extends from the blade holder **520** from a distal terminus **538** onto handle **512** to a proximal terminus **540** on one side of the scalpel. Preferably, scalpel **510** has a groove **536** on each of a first side **537** and a second side **539**, each with distal termina **538** on blade holder **520** and proximal termina **540** on handle **512**. Cantilever **532** further includes at least one boss **542**, preferably two bosses **542**, best seen in FIG. **39**, disposed to engage each of grooves **536**. Each termina of groove **536** is preferably an upward enlargement disposed to engage bosses **542** when shield **530** is positioned in either the proximal or distal positions. When bosses **542** are engaged in the termina, shield **530** is substantially prevented from movement. When the practitioner applies sufficient downward force to digital application section **534** to deflect cantilever **532**, bosses **542** are no longer engaged with the upward enlargements at the termina, thereby allowing the practitioner to selectively move shield **530** between the proximal and distal positions as desired. Bosses **542** track in grooves **536** to stabilize shield **530** during the movement between positions, and when a terminus is reached, bosses **542** preferably serve to provide a practitioner perceptible "snap" as the bosses engage the enlargement and allow cantilever **432** to return to the rest position to assist the practitioner in recognition of the completion of desired movement of the shield. Preferably, termina **538** and **540** each include a roof portion **541** that substantially prevents boss **542** from upward disengagement from the termina.

Additionally, upward distal termina **538** has a distal surface **590** and a proximal surface **591**, each with an upwardmost edge **593** and a lower edge **595**. Preferably, the distance between the upwardmost edges **593** is greater than the distance between the lower edges, thereby causing a distal upward pitch to surface **590** and a proximal upward pitch to surface **591**. The distal upward pitch of surface **590** and proximal upward pitch of surface **591** serve to substantially retain boss **542** in upward distal terminus **538** until the practitioner applies sufficient direct downward force to digital activation section **534** to downwardly deflect first cantilever **532**.

In this embodiment, preferred first cantilever **532** extends distally from proximal end **560** of shield **530**. Referring to FIGS. **40***a* and **40***b*, which is are schematic representations of a portion of shield **430** of the embodiment shown in FIGS. **25–36***c*, and FIGS. **40***c* and d, that are schematic representations of a portion of shield **530** as illustrated in FIGS. **37–39**, the reason for the preferred configuration of cantilever **532** is seen. In the embodiment of shield **430** with cantilever **432**, if a practitioner inadvertently applies proximal force F_i to the distal application section **434** during the mounting of cartridge **418** onto handle **412**, resultant moment M is seen in FIG. **40***b* with a concomitant resultant to move boss **432** downwardly from distal termina **438** thereby potentially, if the force is sufficient, inadvertently releasing shield **430** for proximal movement to expose blade **426**. Referring now to FIGS. **40***c* and **40***d*, illustrating the preferred configuration of cantilever **532**, it is apparent that the application of the same proximal force F_i to digital application section **534** results in a concomitant resultant to move boss **532** upwardly in distal termina **538**. Diagrams comparing these resultants are seen in FIGS. **40***b* and **40***d*. The upward resultant on boss **532** and the downward resultant on boss **432** are shown in FIGS. **40***d* and **40***b* respectively. The placement of the effective hinges H_{400} and H_{500} of the cantilevers **432** and **532** provide the direction of the resultant action on the bosses **432** and **532**. When the preferred cantilever **532** configuration is coupled with the distal upward pitch of surface **590** and proximal upward pitch of surface **591** in distal upward termina **538** in the preferred scalpel **510**, the probability of an inadvertent release of shield **530** for proximal movement during mounting of cartridge **518** onto handle **512** is substantially reduced.

Referring again to FIGS. **37–39***c*, additional ergonomic features to direct the practitioner's finger placement during mounting of the cartridge to the handle are shown. A finger placement surface **598***a* is preferably present on each of a first side **537** and a second side **539** of shield **530**, with several other preferred configurations illustrated as **598***b* and **598***c* in FIGS. **38***a*, **38***b*, and **38***c*. In preference testing, configuration **598***c* is most preferred and includes a preferably roughened surface finish difference from preferably transparent sides **537** and **539** to provide a visual direction and to facilitate the practitioner's grip during mounting and dismounting of cartridge **518** to handle **512**.

In FIGS. **38***b* and **38***c*, a more preferred configuration for digital activation section **534***a* is illustrated. This more preferred configuration reduces any inadvertent force applied by the practitioner to cantilever **532** during mounting cartridge **518** to handle **512**, while facilitating the intention movement of shield **530** to the proximal position to expose blade **526** for its intended use.

A further element to substantially further reduce the possibility of inadvertent proximal movement of shield **530** during mounting of cartridge is best seen in FIGS. **38***a*, **38***b* and **38***c*. A second cantilever **599** is disposed on the bottom of shield **530**. Second cantilever **599** is disposed with a fixed distal end and a free proximal end so that if a practitioner grasps cartridge **518**, in a not recommended manner, at the top and the bottom for mounting cartridge **518** onto handle **512**, second cantilever **599** will be deflected upwardly so that the free end engages blade holder **520** and substantially prevents proximal movement of shield **530**.

Cartridge **518** is preferably supplied sealed in a package **546** illustrated in phantom in FIG. **37** as formed from materials substantially resistant to the passage of microorganisms and exposed to conditions that render any micro-

organisms within the package substantially non-viable. Suitable materials for forming the package include, but are not limited to, paper, polymeric films, non-wovens, metallic foils, and combinations of these materials. Suitable conditions for rendering microorganisms non-viable include, but are not limited to, chemical agents such as ethylene oxide and gaseous hydrogen peroxide, ionizing radiation such as gamma, electron beam, ultra-violet and the like.

Cartridge **518** is supplied separately and includes blade holder **520** and blade **526** in package **546**. Blade **526** is preferably formed from a material such as stainless steel, carbon steel or a ceramic that is suitable for being formed to a sharpened edge for cutting. Shield **530** is substantially not movable with respect to blade holder **520** unless cartridge **518** is properly fully mounted on handle **512** and the practitioner handling the scalpel is intentionally moving the shield. Practitioners and service personnel are thus substantially protected from inadvertent exposure to the blade during assembly of the cartridge to the handle, during handling to prepare for or after a procedure, or during clean-up and disposal of a cartridge after removal from the handle. Shield **530** preferably includes a deflectable tab **550**, seen in phantom in FIGS. **38** *a, b* and *c*, with an inwardly projecting lug **552** that is disposed to engage a seat **554** in blade holder **520**. During initial assembly of cartridge **518**, preferred blade **526** with an aperture **556** is fixedly attached to an outward protuberance **558** on blade holder **520** by fitting aperture **556** over protuberance **558** so that blade **526** is substantially rigid with respect to blade holder **520**. Suitable fixed attachments of blade **526** to blade holder **520** are formed by heat staking the projection onto the aperture, adhesive bonding or the like. Shield **530** has a proximal end **560** and a distal end **562**. The assembly then includes substantially axially aligning proximal end **560** of the shield with distal end **524** of the blade holder and proximally advancing the shield onto the blade holder to form cartridge as shown in FIG. **37**. Tab **550** with inwardly projecting lug **552** is disposed to engage seat **554** in blade holder **520** when bosses **542** are in distal termina **538**, thus substantially preventing further movement of shield **530** with respect to blade holder **520** until cartridge **518** is mounted onto handle **512**.

Preferably, shield **530** is substantially prevented from movement with respect to blade holder **520** during mounting of cartridge **518** onto handle **512** even if the practitioner unintentionally applies sufficient pressure to digital activation surface **545** to deflect cantilever **532**. Proximal end **514** of handle **512** is preferably disposed to engage at least one of bosses **542** as cartridge **518** is proximally advanced onto handle **512** when cantilever **532** is deflected downwardly. Additionally if the practitioner were to inadvertently apply pressure to digit activation surface **534** after cartridge **518** is partially properly advanced onto handle **512**, preferred handle **512** further includes a recess **566** disposed on a top surface **567** of handle **512** to engage at least one of bosses **542** to function as a false stop and substantially prevent further advancement of cartridge **518** onto handle **512**.

As cartridge **518** is fully seated on handle **512**, a distal prong **578** on handle **512** with a chamfered surface **570** is preferably disposed to engage tab **550** and disengage inwardly projecting lug **552** from seat **454** on blade holder **520**, thus allowing movement of shield **530** with respect to blade holder **520** when the practitioner intentionally applies sufficient pressure to digital activation surface **534** to downwardly deflect cantilever **532**. Preferably, distal prong **578** is stiffened by a rib **579** on one side.

Cartridge **518** is releasably mounted to handle **512** by engaging a downward projection **580** on handle **512** with a pocket **582** on a flexible beam portion **584** that projects proximally from blade holder **520**. To remove cartridge **518** from handle **512**, cartridge **518** is distally advanced from handle **512**. Preferably, shield **530** substantially surrounds blade holder **520** and substantially prevents inadvertent access to blade **526** when shield **530** is in the distal position. When shield **530** is proximal, blade **526** is exposed for use, bosses **542** are disposed in proximal termina **540** and shield **530** surrounds at least a portion of handle **512**. Since shield **530** substantially surrounds at least a portion of the handle when is in the proximal position, beam **584** is substantially prevented from flexing downwardly to release projection **580** from pocket **582** by the shield, thus substantially preventing cartridge **418** from being dismounted from handle **512** when the blade is exposed. Additionally, if a practitioner inadvertently applies distal force to attempt to move the shield to the distal position, the presence of bosses **542** in proximal termina **540** substantially prevent movement of shield **530** to the distal position. To move shield **530** to the distal position, the practitioner must apply sufficient force to the digital activation surface **534** to downwardly deflect cantilever **532** and release bosses **542** from the proximal termina **540**. If a practitioner grasps shield **530** and attempts to remove cartridge **418** from handle **412** after shield **430** is released from the proximal position, but before shield **530** is fully seated in the distal position and blade **526** is substantially protected from inadvertent access, shield **530** substantially prevents the disengagement of pocket **582** from projection **580** until the shield is distally advanced to substantially protect blade **526** from inadvertent access. Then, as handle **512** is separated from cartridge **518**, prong **578** is disengaged from tab **550** thereby allowing lug **552** to engage seat **554** and substantially prevent movement of shield **530** with respect to blade holder **520**.

Preferably, shield **530** includes inwardly projecting rails **586** disposed to slidably engage conjugate slots **588** on both sides of blade holder **520** and handle **512** to provide stability to shield **530** during movement between the proximal and distal positions and to improve the overall rigidity and feel of scalpel **510** in the practitioner's hand.

Blade holder **520** may be formed from materials such as polymeric resins or metallic materials. Preferably, blade holder **520** is formed from thermoplastic materials such as polypropylene, polyethylene, polycarbonate, polysulfone, polyacetal, polyamide and the like. Shield **530** may be formed from thermoplastic materials such as polypropylene, polyethylene, polycarbonate, polyacetal, polyamide and the like. For particular applications, the material selected to form shield **530** may be substantially transparent. Handle **512** may be formed from thermoplastic materials such as polyethylene, polycarbonate, polysulfone, polypropylene, polyacetal, polyamide and the like. Preferably, handle **512** is formed from a metallic material such as formed powdered metal or machined metal. Preferably materials are selected to provide a substantially rigid structure for scalpel **510** that are compatible with most sterilization methods and provide practitioners with a scalpel that has similar "feel" and "balance" to current reusable devices or reusable handle devices intended to mount and dismount bare single-use blades.

In normal use, practitioners would receive cartridge **518** sealed in package **546**. A method for assembling scalpel **510** includes opening package **546** to expose cartridge **518**, and positioning the cartridge so that proximal end **522** of the blade holder is in substantial axial alignment with the distal end of handle **512**. The practitioner then advances the cartridge proximally onto the handle until it is fully seated.